Section C 510(k) Summary (21 CFR 807.92)

JUL 27 2011

510(K) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K111752 " (applicant leave blank)

Premarket Notification [510(k)] Summary

Submitter's name :	Shandong jianhong new material company
Submitter's address :	Xisha,Guoli Town,Huantai County,Zibo City, Shandong Province, 255000,China
Phone number :	0086-533-8437998
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Name of contact person:	Mr.Tian Jianguo
Date the summary was prepared:	May 10, 2011

Device Name:	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Proprietary/Trade name:	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) Other clients private labeling
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LYZ

Class I* Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) that meets all of the requirements of ASTM standard D 5250-06e1.

Predicate device: Powder-Free Vinyl Patient Examination Gloves, Clear (Non-colored), ZHANG JIA GANG FENGYUAN PLASTIC PRODUCTS CO LTD. K091663.

Device Description: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) that meets all of the requirements of ASTM standard D 5250-06e1.

Device Intended Use (indication for use): Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

A summary of the technological characteristics of new device compared to the predicate device.

The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 5250-06 e1.	Meets
Physical Properties	ASTM standard D 5250-06 e1.	Meets
Freedom from pinholes	21 CFR 800.20	Meets
Powder Residual	ASTM standard D 5250-06 e1 and D6124-06	Meets <2mg/glove
Biocompatability	Primary Skin Irritation in rabbits AAMI / ANSI / ISO 10993-10	Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig AAMI / ANSI / ISO 10993-10	Passes Not a Dermal sensitization

A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), meet requirements per ASTM D5250-06 e1, per ASTM D6124-06, per 21 CFR 800.20 and FDA recognition number 2-152: AAMI / ANSI / ISO 10993-10:2002/Amd. 1:2006.

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

Conclusions

It can be concluded that the Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims.

It can be concluded that the Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is as safe, as effective, and performs as well as the predicate device, Powder-Free Vinyl Patient Examination Gloves, Clear (Non-colored), ZHANG JIA GANG FENGYUAN PLASTIC PRODUCTS CO LTD.K091663.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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JUL 27 2011

Re: K111752
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: July 1, 2011
Received: July 8, 2011

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOf fices/CDRH/C DRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProbl em/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111752

Section B Indications for Use

INDICATIONS FOR USE

Applicant: Shandong jianhong new material company

510(k) Number (if known): *

Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)

Indications For Use:

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111752